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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,970	10/16/2003	Rudolf Pachl	5727-73662	8089
49437	7590	06/14/2006		
BARNES & THORNBURG LLP 11 SOUTH MERIDAN STREET INDIANAPOLIS, IN 46204			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT	PAPER NUMBER

1743

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/686,970	PACHL ET AL.	
	Examiner	Art Unit	
	Lore Ramillano	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 19-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/1/04, 10/7/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. In applicant's amendment filed on 10/16/03, applicant amended the specification; cancelled claims 1-18; and added new claims 19-33. Claims 19-33 are pending in the application.

### Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claim 19** is rejected under 35 U.S.C. 102(e) as being anticipated by Petrich et al. (US 6362890).

The applied reference has a common assignee, Roche Diagnostics GmbH, with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Petrich et al. teach a method comprising: operating an optical measuring device to determine the amount of the sample placed on the test element based on an interaction between a control substance disposed on the test element and a sample matrix of the sample, and operating the optical measuring device to determine the analyte content of the sample based on an interaction between a reagent disposed on the test element and the analyte in the sample. (column 4, lines 13-41).

4. **Claims 19-22** are rejected under 35 U.S.C. 102(e) as being anticipated by Modzelewski et al. (US 6541266).

Modzelewski et al. teach a method comprising: operating an optical measuring device to determine the amount of the sample placed on the test element based on an interaction between a control substance disposed on the test element and a sample matrix of the sample, and operating the optical measuring device to determine the analyte content of the sample based on an interaction between a reagent disposed on the test element and the analyte in the sample. (column 5, lines 6-26).

Modzelewski et al. further teach a method comprising: operating the optical measuring device to correct the analyte content of the sample if the amount of the sample placed on the test element is determined to be less than a predetermined calibration value (column 12, lines 4-16); determining the amount of the sample placed on the test element includes assessing a volume of blood placed on the test element (column 5, lines 6-26); and determining the analyte content of the sample includes determining the glucose content of the sample (column 4, lines 39-56).

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5. **Claims 23-25** are rejected under 35 U.S.C. 102(e) as being anticipated by Modzelewski et al.

Modzelewski et al. disclose a system comprising: an optical measuring device that includes (i) a light emitter device that generates a first photometrically detectable signal upon interacting with a reagent disposed on the test element after the reagent interacts with an analyte contained in a sample disposed on the test element and a second photometrically detectable signal upon interacting with a control substance disposed on the test element after the control substance interacts with a sample matrix of the sample disposed on the test element and (ii) a light detector device that receives the first photometrically detectable signal and the second photometrically detectable signal; and an electronic circuit wherein the electronic circuit is configured to: analyze the first photometrically detectable signal from the optical measuring device to determine the analyte content of the sample based on the concentration of the analyte in the sample, and analyze the second photometrically detectable signal from the optical measuring device. (column 5, line 45 to column 6, line 58).

Modzelewski et al. further disclose a system wherein the electronic circuit is further configured to correct the analyte content of the sample if the amount of the sample placed on the test element is determined to be less than a predetermined calibration value. (column 12, lines 4-16).

Modzelewski et al. further disclose a system wherein the electronic circuit is configured to analyze the first photometrically detectable signal from the optical measuring device to determine the glucose content of the sample, and analyze the

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second photometrically detectable signal from the optical measuring device. (column 5, line 45 to column 6, line 58).

6. **Claims 26-27** are rejected under 35 U.S.C. 102(e) as being anticipated by Modzelewski et al.

Modzelewski et al. disclose an analyte evaluation instrument, comprising: an optical measuring device, and an electronic assembly electrically coupled to the optical measuring device (column 4, lines 39-56; column 5, lines 27-44).

7. **Claims 28-31** are rejected under 35 U.S.C. 102(e) as being anticipated by Modzelewski et al.

Modzelewski et al. disclose a system comprising: a test element having (i) a test field for accepting the sample, (ii) a reagent in the test field, wherein the interaction between the reagent and the analyte (glucose) causes a first photometrically detectable signal to be produced when the test field is illuminated with light, and (iii) a control substance in the test field (column 4, lines 39 to column 5, line 26); an optical measuring device that includes (1) a light emitter device and (ii) a light detector device; and an electronic assembly electrically coupled to the optical measuring device (column 5, lines 44-55).

8. **Claims 32-33** are rejected under 35 U.S.C. 102(e) as being anticipated by Modzelewski et al.

Modzelewski et al. disclose a test element comprising: a test field; a reagent in the test field; and a control substance in the test field (column 4, lines 39 to column 5, line 26).

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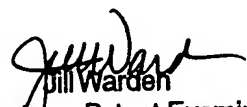
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano  
Examiner  
Art Unit 1743

6/10/06

  
Jill Warden  
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Technology Center 1700